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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,515	09/25/2003	Peter Adorjan	5013.1022CIP	1178
23280	7590	11/02/2005	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			NEGIN, RUSSELL SCOTT	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/672,515	Applicant(s) ADORJAN ET AL.	
	Examiner Russell S. Negin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-52, drawn to a method for selecting epigenetic features, classified in class 702, subclass 19. If this group is chosen, then the below mentioned species elections are required.
- II. Claims 53-97, drawn to a computer readable medium having stored on it method for selecting epigenetic features, classified in class 702, subclass 19. If this group is chosen, then the below mentioned species elections are required.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus or by hand. For example, Group I can be practiced in theory by hand, making it distinct from the computer reading medium in Group II.

SPECIES ELECTIONS FOR GROUP I:

Applicant must elect one specie from each category.

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Category #1

Specie 1-A: the biological sample is divided into two phenotypic classes of interest.

(Claims 10-11)

Specie 1-B: the biological sample is divided into more than two phenotypic classes of interest. (Claim 1)

Generic to this category: Claims 1-9, 12-52.

Reason: Dividing into more than two phenotypic classes presents a level of complexity to analysis not inherent in the simpler case of dividing the sample into two phenotypic classes of interest.

Category #2

Specie 1-C: principal component analysis is performed to determine the candidate set of epigenetic features. (Claim 17)

Specie 1-D: multidimensional scaling is performed to determine the candidate set of epigenetic features. (Claim 18)

Specie 1-E: isometric feature mapping is performed to determine the candidate set of epigenetic features. (Claim 19)

Specie 1-F: cluster analysis is performed to determine the candidate set of epigenetic features. (Claim 20-22)

Specie 1-G: predetermined biological information is used to define the candidate set of epigenetic features. (Claim 23-24)

Generic to above: Claims 1-16, 25-52

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Category #3:

Specie 1-H: selection criterion includes a training error of the machine learning classifier (Claim 25)

Specie 1-I: selection criterion includes a risk of the machine learning classifier (Claim 26)

Specie 1-J: selection criterion includes a bound on a risk of the machine learning classifier (Claim 27)

Specie 1-K: selection criterion includes a statistical test (claims 28-34)

Specie 1-L: selection criterion includes a Fisher criterion (Claim 35)

Specie 1-M: selection criterion includes weights of a linear discriminant (claims 36-38)

Specie 1-N: selection criterion includes an average pairwise correlation (claim 40)

Specie 1-O: selection criterion includes mutual information between phenotypic classes of interest. (Claim 41)

Specie 1-P: selection criterion includes subjecting epigenetic feature data corresponding to the candidate set of epigenetic features of interest (claim 39)

Specie 1-Q: selection criterion includes a number of correct classifications (claim 42)

Specie 1-R: selection criterion includes eigenvalues of the principle components (Claim 43)

Generic to Category #3: Claims 1-24, 44-52

Reason: Each criterion is a distinct method of evaluating a criterion relating to the epigenetic feature of interest.

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Category #4:

Specie 1-S: selecting the highest ranking epigenetic features is accomplished by selecting the highest ranking epigenetic features of interest. (Claim 44)

Specie 1-T: selecting the highest ranking epigenetic features is accomplished by excluding the lowest ranking epigenetic features of interest. (claim 45)

Specie 1-U: Selecting the highest ranking epigenetic features of interest is performed by selecting a feature criterion score greater than the defined threshold. (claim 46)

Specie 1-V: Selecting the highest ranking epigenetic features of interest is performed by selecting a feature criterion score lower than the defined threshold. (claim 47)

Generic to #4: claims 1-43, 48-52

Reason: Each criterion for selecting the highest ranking epigenetic feature is unique and imposes a different method selecting the highest ranking epigenetic features.

SPECIES ELECTIONS FOR GROUP II:

Applicant must elect one specie from each category.

Category #5:

Specie II-A: candidate of epigenetic features is the set of all subsets of the defined epigenetic features of interest (claim 58)

Specie II-B: candidate of epigenetic features is the set of all subsets of a given cardinality of the defined epigenetic features of interest (claim 59)

Specie II-C: candidate of epigenetic features is the set of all subsets of a cardinality of 1 of the defined epigenetic features of interest (claim 60)

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Generic to the above: claims 53-57, 61-97

Category #6:

Applicant must choose a method of defining the candidate set of epigenetic features of interest. He must choose one from the following sets: 61, 62, 63, {64-66}, {67-68}, 69, 70, 71, {72-78}, 79, {80-82}, 83. Each claim (or set of claims) imposes a different method of defining the epigenetic feature selection. Claims 53-60 and 84-97 are generic to the above category.

Category #7:

Applicant must choose the appropriate epigenetic feature selection criterion. Each claim (84, 85, 86, 87, 88) imposes a different method of epigenetic feature selection of which the applicant must choose one. Each method of feature selection is distinct and unique. Claims 53-83 and 89-97 are generic to the above category.

Category #8:

Specie 2-S: selecting the highest ranking epigenetic features is accomplished by selecting the highest ranking epigenetic features of interest. (Claim 89)

Specie 2-T: selecting the highest ranking epigenetic features is accomplished by excluding the lowest ranking epigenetic features of interest. (claim 90)

Specie 2-U: Selecting the highest ranking epigenetic features of interest is performed by selecting a feature criterion score greater than the defined threshold. (claim 91)

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Specie 2-V: Selecting the highest ranking epigenetic features of interest is performed by selecting a feature criterion score lower than the defined threshold. (claim 92)

Generic to #8: Claims 53-88, 93-97.

Reason: Each criterion for selecting the highest ranking epigenetic feature is unique and imposes a different method selecting the highest ranking epigenetic features.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ardin Marschel, Ph.D., Supervisory Patent Examiner, can be reached at (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. Negin 10/28/05

Russell Negin 10/28/05

Ardin H. Marschel 10/29/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER